ACCELERATE YOUR GxP COMPLIANCE IN THE CLOUD

WHAT TO EXPECT FROM YOUR TECHNOLOGY PROVIDER

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CONTENTS

▶ For more detailed information, read **How Appian Supports GxP in the Cloud**

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INTRODUCTION

Your commitment to GxP is unassailable. Whether addressing Good Laboratory Practices (GLP), Good Clinical Practices (GCP) or Good Manufacturing Practices (GMP), your life sciences organization has implemented the necessary critical quality measures for compliance.

And when “computerized systems” are used to perform or support GxP activities, you ensure they are designed, developed, validated, operated, and maintained appropriately for the intended use of the system.

Maintaining this compliance is fundamental to your operations. Maintaining this compliance in the cloud is a new challenge.

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INTRODUCTION

The ability to effectively maintain compliance while operating in the cloud has become critical to success, as Life Sciences leaders increasingly move to include GxP activities in cloud applications in order to innovate and streamline research and development, and speed time to market and value to the patient.

Read on to learn more about cloud advantages and challenges for Life Sciences, and the approaches and best practices to consider that will help maintain GxP compliance while operating in the cloud.

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1 THE ADVANTAGES OF CLOUD COMPUTING

The cloud promises important advantages like scalability and speed to deploy new capabilities.

> Cloud has become increasingly popular across industry sectors.
> The recent Appian survey conducted by Harris Poll to IT decision makers found:
>
> ***"A majority (70%) of the respondents believe cloud-based applications/solutions will provide the top returns in 2016."***

But cloud is about more than just efficiency. Perhaps the greatest value of cloud computing to a research-intensive industry like Life Sciences is that cloud computing can facilitate innovation. The cloud can provide a platform for collaboration and even harmonization across global transactional processes.

Forward thinking Life Sciences organizations are exploring the potential of cloud computing in research, development, supply chain and commercial areas.

And, as the move to cloud includes important applications, leaders must likewise ensure that the challenge of maintaining GxP compliance is met.

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2 THE CHALLENGE OF MAINTAINING GxP COMPLIANCE IN THE CLOUD

> ***"Poisons and medicine are often the same substance given with different intents."***
> – Peter Mere Latham, medical educator
>
> ***"Compliance to good practices assures your best intentions are always met."***
> – Evi Cohen, Appian Global Practice Leader, Life Sciences

We depend on medicine everyday...we depend on medicine to help us, not harm us. GxPs practices ensure that medicine is safe to use and efficacious, in other words, does no harm and provides treatment as intended.

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2 THE CHALLENGE OF MAINTAINING GxP COMPLIANCE IN THE CLOUD

Achieving and maintaining compliance with GxPs is essential not only for the safety of your consumers, but also for the reputation, quality, and stability of your company. Digital transformation strategies aim to improve and accelerate your processes...for faster time to market, and value to the patient...but executing to that objective can prove to be near-impossible with technology solutions that aren't flexible to your company's changing needs and to the critical validation requirements within your industry.

Running in the cloud adds another dimension to those critical validation challenges. How do you ensure the integrity of data used to make product-related safety decisions when you operate in the cloud?

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3 BEST PRACTICES IN MEETING YOUR COMPLIANCE RESPONSIBILITIES

On a good day, your systems do exactly what you designed them to do (verification). On a great day, their design is also correct, complete, and auditable (validation). As a Life Sciences company, you can't afford to wait around for occasional great days.

Maintaining compliance in the cloud cannot be simply assigned to your cloud provider nor can you achieve compliance unilaterally – at the end of the day the sponsor is accountable in front of the regulators, but the execution and responsibilities must be shared.

3 BEST PRACTICES IN MEETING YOUR COMPLIANCE RESPONSIBILITIES

You are required by law to meet Validation and Good Practice Standards (GxP) when building systems for Clinical Trials, Quality Assurance, Regulatory Information Management, Manufacturing, or Electronic Health Records. The requirements for compliance in the cloud are the same as for on premise. 21 CFR Part 11, outlining validation and other requirements for electronic systems that handle electronic records, when those are required by regulations, of course, also applies. Yet there are additional considerations to keep in mind to ensure that the technology used for regulating pharmaceutical processes is meeting GxP validation requirements.

The FDA defines electronic system validation as,

"confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled."

Such confirmation is achieved through:

- Planning and coordinating system requirements
- Verification and testing to meet software requirements
- Ensuring traceability with reliable documentation

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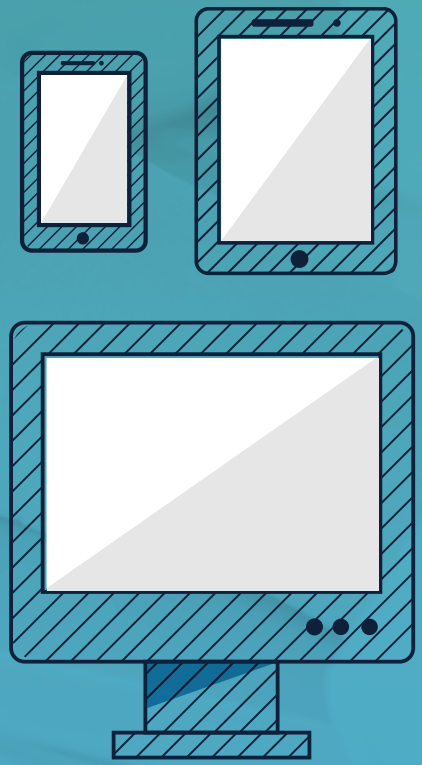
3 BEST PRACTICES IN MEETING YOUR COMPLIANCE RESPONSIBILITIES

To stay in control of GxP in the cloud, apply these basic best practices and ensure your technology partners work with you to achieve compliance:



1. Establish Service Level Agreements (SLAs)

   First and foremost ensure you have the proper SLAs as a foundation. In order to benefit from adopting the cloud, organizations with Good Laboratory, Clinical or Manufacturing Practices (GxP) compliance requirements and their auditors will need to be assured that service levels will be met so that they can focus on application technology choices that make compliance more agile, automated and security-oriented in the cloud.

2. Monitor change

   Look for change control capabilities as you evaluate your GxP related cloud technology. Managing the documents associated with the processes in a validated system is critical. However, the technology should have control mechanisms that extend to both documents and processes.

3 BEST PRACTICES IN MEETING YOUR COMPLIANCE RESPONSIBILITIES

3. Ensure audit trails

The ability to provide a comprehensive audit trail and trace business data is critical to GxP compliance. Look for cloud technology where every action performed in a running process instance is logged into a secure audit trail. The audit trail should also provide historical tracking of changes to all data elements, including who made the changes, at what date and time they occurred, and to what value. Look as well for audit information that can be securely retrieved by a System Administrator in an easy to understand format, and pushed to other reporting, auditing or logging systems.

3 BEST PRACTICES IN MEETING YOUR COMPLIANCE RESPONSIBILITIES

4. Choose flexible application technology

Packaged solutions must be validated before distribution. The problem? Your needs and requirements change, and your boxed solution is not flexible enough to keep up. And forget about looking to future modernization; connection to other cloud systems and mobility are impossible for systems that can't evolve. If you don't choose the right cloud application technology, you will be faced with the additional pain and cost downstream to maintain GxP as your business evolves. The way to mitigate that risk? Choose a flexible digital platform, powered by Business Process Management.

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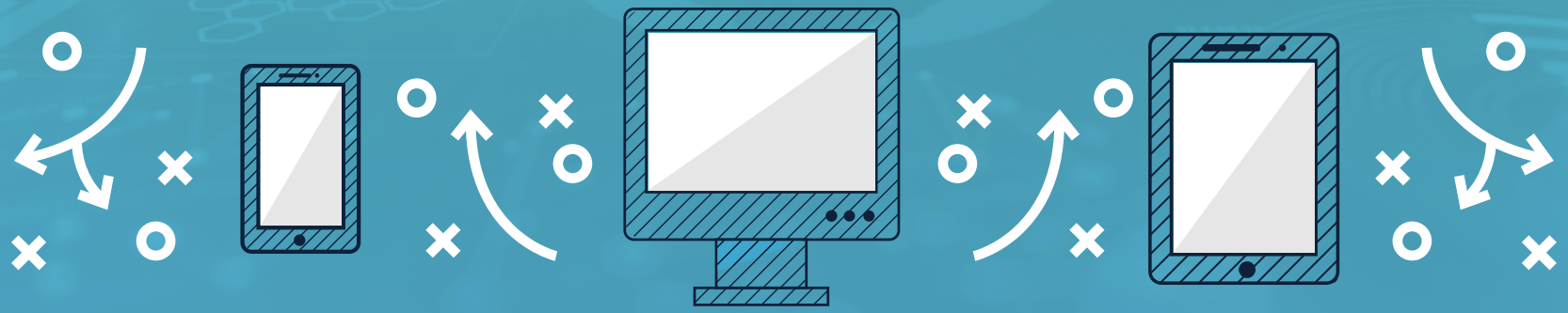
4 IMPROVING SPEED AND QUALITY WITH A DIGITAL PLATFORM

Now, imagine implementing a digital transformation strategy to meet your organization's needs today and into the foreseeable future, without assuming all the headaches of validation from scratch.

CASE STUDY

A major pharmaceutical firm is leveraging Appian's digital application platform in the cloud to provide for a majority of the IQ (installation qualification) and PQ (performance qualification) requirements and allow them to concentrate on the OQ (operational qualifications) of the business solution itself.



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4 IMPROVING SPEED AND QUALITY WITH A DIGITAL PLATFORM

Using a digital platform in the cloud to develop critical applications offers compliance flexibility and agility. Further, a platform powered by BPM has the ability for organizations to merge data and processes, allowing for real-time data input and transfer. This seamless integration makes the pharmaceutical development process more efficient, traceable and transparent. The process traceability and transparency, in turn, provide information feedback that is needed for requirement validation.

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4 IMPROVING SPEED AND QUALITY WITH A DIGITAL PLATFORM

Issues arise when validating systems that are pre-built for generic pharmaceutical requirements. Their computer code must be deconstructed and understood before it can be validated, draining time and money from your company.

Instead, **fit-for-purpose applications** that are constructed with an easy to understand **low-code design** are much simpler to validate. And **the right digital application platform** in the cloud enhances accuracy of data and speed of development and implementation.

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CONCLUSION

Meeting good practices – whether on premises or in the cloud – requires diligence and technology partners that are focused on flexibility and quality. Appian is dedicated to configuring solutions for the Life Sciences industry that satisfy Title 21 CFR Part 11 requirements as well as GxP – GMP, GCP, GLP and GAMP.

GxP compliance in the cloud is a reality. It requires proper planning and the right technology partners. Choose a partner that will help you execute to your best intentions; one that:

- Remains knowledgeable about the GxP regulations and requirements placed on a technology vendor to the Pharma industry
- Undergoes GxP risk assessments regularly and maintains a strong and diligent audit readiness state
- Provides a digital application platform to supports the development of compliant and validated solutions, that also meet strict requirements of 21 CFR Part 11

Ready to take control of GxP in the cloud?
Learn more about Appian's approach to GxP at the Appian Trust Center.

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APPIAN FOR LIFE SCIENCES

Appian delivers an enterprise platform for digital transformation that speeds time to market and value to the patient. Powered by industry leading capabilities, Appian's approach radically accelerates the time it takes to build and deploy powerful, modern applications, on-premises or in the cloud. The world's most innovative Life Sciences organizations use Appian to revolutionize their customer experiences, transform their operations, and master regulatory compliance. For more information, visit ***www.appian.com.***

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